

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property  
Organization  
International Bureau



(43) International Publication Date  
17 June 2004 (17.06.2004)

PCT

(10) International Publication Number  
**WO 2004/049966 A2**

- (51) International Patent Classification<sup>7</sup>: **A61C**
- (21) International Application Number:  
PCT/US2003/038427
- (22) International Filing Date: 3 December 2003 (03.12.2003)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:  
10/309,831 4 December 2002 (04.12.2002) US
- (71) Applicant and  
(72) Inventor: WASYLUCHA, Bryan [US/US]; 2222 Michelson Drive, #222-447, Irvine, CA 92612 (US).
- (74) Agents: POSA, John, G. et al.; Gifford, Krass, Groh, Sprinkle, Anderson & Citkowski, P.C., 280 N. Old Woodward Avenue, Ste. 400, Birmingham, MI 48009 (US).
- (81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR,

CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

- (84) Designated States (*regional*): ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

**Published:**

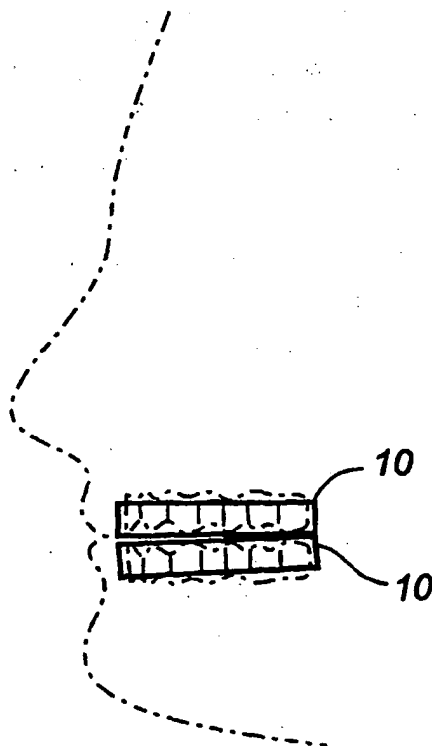
— without international search report and to be republished upon receipt of that report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: METHOD AND APPARATUS FOR BLEACHING TEETH

(57) **Abstract:** A method and apparatus for whitening teeth which allow the user to undergo dental bleaching with the mouth closed and without protruding instruments, trays or electrical wires and the like. The apparatus includes a support structure and a dental whitening composition in contact with the support structure. A light source is included in the apparatus, disposed on or in the support structure so that light emitted from the source contacts on the dental whitening composition. The apparatus has a volume ranging between 0.5 - 450 cm<sup>3</sup> permitting the apparatus to fit entirely within the mouth of a user during treatment.

WO 2004/049966 A2



- 1 -

## METHOD AND APPARATUS FOR BLEACHING TEETH

### REFERENCE TO RELATED APPLICATIONS

This application claims priority from U.S. Patent Application Serial No. 10/309,831, filed December 4, 2002, the entire content of which is incorporated herein by reference.

5

### FIELD OF THE INVENTION

This invention relates to methods and apparatus for dental bleaching. In particular the invention relates to methods and apparatus for light accelerated dental bleaching which permit the patient to close the mouth during treatment.

10

### BACKGROUND OF THE INVENTION

Dental bleaching is an increasingly popular treatment and dentists are constantly searching for techniques that are both convenient and comfortable for their patients. Numerous methods and tools have been developed for the purpose of dental bleaching. Typically, a composition containing hydrogen peroxide is applied to the teeth and allowed to remain in contact with the surface to be bleached. Unfortunately, home treatments usually involve long treatment protocols due to the low strength compositions available for home use. For example, a typical treatment regimen may require twice daily 15 – 30 minute applications of a hydrogen peroxide, or 1 – 2 hour daily applications of carbamide peroxide, over a period of several weeks.

20

Alternatively, patients are treated in a dentist's office for more intensive treatment using concentrated bleaching compositions. Disadvantages of these treatments include the inconvenience of remaining in the dental office, often with uncomfortable clamps, dams and retractors affixed to the mouth to keep it in the proper position. Not surprisingly, much effort has been expended in the search for methods of increasing the comfort, convenience and speed of the bleaching process. Various methods and devices have been developed to this end, broadly including those that expose a whitening composition to heat, light or a combination of these. However, such methods and devices require that a user remain in one place with the mouth open, or attached to a heater or light source that extends from the mouth. Thus, there exists a need for methods and

25

- 2 -

apparatus for bleaching teeth that accelerate treatment, allow the patient to move freely during treatment, and avoid the inconvenience of having any part of the treatment apparatus protruding from the mouth.

#### SUMMARY OF THE INVENTION

5 A dental apparatus is provided including a support structure adapted to be placed entirely within a user's mouth, a dental whitening composition in contact with the support structure, and a light source disposed on or in the support structure such that light emitted from the source impinges on the dental whitening composition. The apparatus has a volume ranging between  $0.5 - 450 \text{ cm}^3$ .

10 The dental whitening composition includes an oxidizing agent which is optionally a peroxide. The composition may be supplied in the form of a gel, emulsion, gum, putty, liquid, paste or a microencapsulated form such as agar gel beads, liposomes and niosomes.

The light source may be a luminescent material such as a phosphorescent, 15 chemiluminescent or phosphorescent substance or a combination of these. The light source may also be a diode, such as light emitting diode or laser diode or a combination of a diode and a luminescent material. Optionally, the light source is in the form of a gel, gum, emulsion, putty, glow tube, glow stick, liquid, varnish, powder, crystalline solid, pellet, aggregate, curable resin or paste.

20 The support structure may take any of various forms including a dental strip or a dental tray. Optionally, the support structure includes a reflective material disposed on the structure such that light is reflected toward the whitening composition.

A method is provided for treating a dental surface of a user which include the steps of providing a dental apparatus that has a support structure adapted to be placed 25 entirely within the user's mouth, a dental whitening composition in contact with the support structure, and a light source disposed on or in the support structure such that light emitted from the source impinges on the dental whitening composition. The apparatus has a volume between  $0.5 - 450 \text{ cm}^3$ . In another step included in the method, the light source is activated so that light is emitted by the light source. The apparatus is placed 30 entirely within the user's mouth and then the dental surface to be treated is exposed to the light emitted by the light source, thereby treating the dental surface.

- 3 -

## BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1A is a drawing illustrating a side view of an embodiment of an inventive apparatus in place inside a user's mouth;

Figure 1B is a drawing illustrating a perspective view of an inventive apparatus;

5 Figure 2A is a drawing illustrating a side view of an embodiment of an inventive apparatus in place inside a user's mouth;

Figure 2B is a drawing illustrating a textured surface of a support structure;

Figure 2C is a drawing illustrating a textured surface of a support structure;

Figure 2D is a drawing illustrating a textured surface of a support structure;

10 Figure 2E is a drawing illustrating an individual cell included in a textured surface of a support structure;

Figure 2F is a drawing illustrating a cross-section of a textured surface of a support structure;

15 Figure 2G is a drawing illustrating a cross-section of a textured surface of a support structure;

Figure 3A is a drawing illustrating an embodiment of an inventive apparatus;

Figure 3B is a drawing illustrating an embodiment of an inventive apparatus;

Figure 3C is a drawing illustrating an embodiment of an inventive apparatus;

Figure 3D is a drawing illustrating an embodiment of an inventive apparatus;

20 Figure 4 is a flow diagram illustrating steps included in a method of bleaching a dental surface; and

Figure 5 is a drawing illustrating an embodiment of an inventive apparatus.

## DETAILED DESCRIPTION OF THE INVENTION

Dental Apparatus

25 An apparatus according to the present invention includes a support structure, a dental whitening composition, and a light source. The apparatus is adapted to be contained entirely within the closed mouth of a user, such that the apparatus operates to whiten teeth in the closed mouth of a user without any part of the apparatus protruding from the mouth. This allows the user to rest comfortably while receiving the benefits of  
30 dental whitening. Figures 1A and 2 illustrate embodiments of the apparatus 10 in place in a user's mouth.

- 4 -

## Support Structure

### Form of a Support Structure

The support structure may have any of various forms determined according to the form of whitening composition used, choice of dental surface to be treated, the number of dental treatments to be performed and the length of time over which a single dental treatment is performed. Support structures for dental treatment are known in the art and illustratively include a strip of sheet material and a shaped dental tray approximating the shape of a tooth, part or all of a dental arch or both dental arches. A typical dental tray has a U-shape in order to fit the average dental arch and channels are formed therein for insertion of the teeth during treatment. Figure 1A illustrates an embodiment of the apparatus 10 in place in a user's mouth wherein the support structure has the form of a dental tray. Figure 1B illustrates a U-shaped support structure 12.

Particularly preferred is a support in the form of a tape or strip. Figure 2A illustrates an embodiment of the apparatus 10 in place in a user's mouth wherein the support structure has the form of a sheet material. Further, support structures of the type useful in the present invention are those fabricated to conform to an individual's dentition, as is commonly performed in making dental tools such as bite splints, dental trays for medication delivery etc. The support may be formed to contain, cover or adhere to one tooth or multiple teeth at a time, and one or multiple surfaces of the teeth, such as front and back. This support allows selective treatment, such as treatment of front and back surfaces of front teeth only or treatment of all teeth, as desired. Supports in tape or strip form are known in the art, such as those described in, for example, U.S. Patent Nos. 5,891,453; 5,894,017; 5,989,569 and 6,045,811.

In one embodiment, the support structure includes a reflective material disposed in or on the support structure so as to direct light toward the tooth surface to be whitened. Exemplary reflective materials include a white or silver coating, a metallic surface, metallic particles or metallic insert, so as to direct light toward the tooth surface to be whitened.

A support structure may have one or more textured surfaces. A textured surface promotes the adherence of the structure to the dentition and promotes contact between the whitening composition and the dental surface to be treated. A textured may include bumps or protrusions in a regular or irregular pattern. Generation of a textured surface is by methods known in the art, illustratively including embossing.

- 5 -

Optionally, a support structure includes a reservoir for holding whitening composition to be delivered to the dental surface to be treated. For example, a reservoir may be a textured surface that includes a pattern of shaped individual cells in the support structure surface. Each cell includes a wall defining a shape of the cell, and a central depression. The individual cell may have any shape including a geometric shape such as a circle, oval, a polygon, illustratively including a square, rectangle, triangle hexagon or other regular or irregular shape. Cells included in a support structure may all have the same shape and same size or cells may differ depending on such factors as, for example, the viscosity of the composition used and the dental surface to be treated. Examples are shown in Figures 2B, 2C and 2D, illustrating shaped cells 100, each having a wall 110 and a central depression 120. Typically, an individual cell has a diameter (or a largest dimension) 130 that ranges in length from about 0.1 to 15 millimeters. A central depression 120 ranges in depth from about 0.1 to 4 millimeters. In a preferred embodiment, the cell is hexagon shaped, forming a honeycomb pattern on a surface of the support structure. An example of a preferred hexagonal pattern is shown in Figure 2D. The hexagonal cells forming the honeycomb pattern may all have the same size or may differ in size. In a preferred embodiment, an individual hexagonal cell, as shown in Figure 2E, has 6 sides of equal length, a diameter 130 ranging from about 5 to 6 millimeters and a central depression 120 having a maximal depth of about 0.1 to 4, preferably 2.0, millimeters.

A wall 110 of an individual cell 100 divides one cell from another and defines the central depression 120. A wall 110 may slope towards the central depression 120, as shown in cross-section in Figure 2F, or a wall 110 may have straight sides as shown in cross-section in Figure 2G.

#### Composition of a Support Structure

The support structure may be made of any of the typical biocompatible materials used in forming dental apparatus. Resins, plastics, waxes and the like may be used to form sheet material or a suitable shape by known methods such as injection molding or casting. Thermoset and photocurable materials may be used, particularly for support structures formed to the individual's dentition, as is known in the art. Illustrative examples of synthetic polymers used include polyurethanes, polyvinyl chlorides, acrylates, including ethyl vinyl acrylate, polycarbonate, polyphenylene oxide, polyimide, polyethylene, polypropylene, polystyrene, polyvinyl chlorides, polyamides and

- 6 -

polyesters, acetates including ethyl vinyl acetate, combinations thereof and art recognized equivalents. Natural materials may also be used, including natural waxes, plant fiber materials such as cellulose, and the like. Preferred materials include beeswax and paraffin. Further, mixtures of such materials may be used.

5 For example, a preferred support composition includes paraffin or beeswax. A support in the form of a paraffin or beeswax sheet is moldable such that a dental tray is formed by application of the sheet material to the dentition. Advantageously, a moldable material allows formation of a custom fit dental tray in minutes or less, in some cases almost instantly.

10 The finished support may have a relatively supple consistency such as a gel, foam or wax such that teeth are not damaged by contact therewith. In a preferred embodiment a support structure is has a gel-like consistency. A gel-like support structure may be formed from materials including exemplary materials such as gelatin, silicone, gelled mineral oils, and the like. Further, materials such as the Versagel C or M series  
15 (Penrenco) or other di-block, tri-block, multi-block and radial block copolymers such as the Kraton G series polymers (Shell Chemical) are suitable for use in the invention. Other exemplary materials that may be used include gelled Permethy 99A-750, 99A-753-59, and 99A-753-58 triblock and starburst polymer mixture, OS129880, OS 129881 and OS 129883 from Lubrizol (a styrene/methacrylate copolymer), Viscogel by Laviosa  
20 Chimica Mineraria, silicone products such as Medical Adhesive A, 7-9800, RTB 700,732,736 by Dow Corning and dimethicone copolyols such as Dow Corning 3225C and lauryl methicones such as Dow Corning Q2-5200 all by Dow Corning Company.

Advantageously, the support may include an adhesive for promoting adherence to the dental surface.

## 25 Dental Whitening Composition

### Dental Whitening Composition Ingredients

A dental whitening composition used in an inventive apparatus includes an oxidizing agent. Oxidizing agents used in dental whitening are known in the art and include, for example, a peroxide, an alkali metal percarbonate, an alkali metal perborate  
30 or a combination thereof are illustrative of useful oxidizing agents. Most commonly used peroxides include hydrogen peroxide, carbamide peroxide and alkali metal peroxides.

- 7 -

Concentrations of oxidizing agents as used in dental whitening are known in the art and depend on the circumstances of use as detailed in, for example, U.S. Patent Nos. 5,032,178; 5,409,631; 5,785,527; 6,149,895; 6,155,832; 6,162,055; 6,165,448; 6,231,343; 6,306,370; 6,309,625; 6,312,666; 6,343,933; 6,387,353; 6,440,396; and  
5 6,458,340. A peroxide is typically used at concentrations ranging from 1% to 50%. Typically, lower concentrations of hydrogen peroxide, from 2 - 10% are made available to patients for in home use. Higher concentrations are used in a clinician's office, ranging from 10 - 35%.

The dental whitening composition may further include optional ingredients such  
10 as a buffer, a thickener or gelling agent, a solvent, a surfactant, additives such as flavoring agents or preservatives and other inert customary ingredients as detailed in, for example, U.S. Patents referenced above. A further ingredient of the dental whitening composition is an optional heat or light absorbing component or a reaction accelerator such as a catalyst as detailed in, for example, U.S. Patent Nos. 6,287,120; 6,439,888 and  
15 6,440,396.

A dental composition may also contain a therapeutic agent such as an agent to treat dental or systemic diseases or conditions, including anti-plaque agents, anesthetics, desensitizing agents, analgesics, antibiotics, antifungals, antimicrobials, antivirals, anti-inflammatory agents, steroids, remineralizing agents, and anticarcinogenic agents.

20 Form of a Dental Whitening Composition

The dental whitening composition may be applied to a support and/or to the dental surface to be whitened. The composition may have any of various forms, illustratively including liquid, gel, emulsion, putty or paste. The composition may further be in a microencapsulated form such as alginate beads or agar gel beads, liposomes,  
25 niosomes, or other form in which a boundary layer is formed to surround the whitening composition. Such formulations are known in the art, for example as taught in U.S. Patent Nos. 6,375,985; 6,375,968; 6,319,507; 6,217,908 and Microencapsulation: Methods and Industrial Applications in Drugs and the Pharmaceutical Sciences, Vol. 73; S.Benita (Ed.); Marcel Dekker; 1996. A time-release formulation is also contemplated,  
30 such as that disclosed in U.S. Patent No. 6,197,331, for example.

A dental whitening composition may be conveniently packaged so as to deliver an amount appropriate for a single use. A single use amount will depend on the whitening composition used, the area of the dental surface to be treated and the amount of



- 8 -

whitening desired. Generally, a single use amount will range from 0.1 – 1 or less ml for smaller treatment areas, and between about 2ml to 5ml for larger areas. Larger amounts, ranging from 6ml to 15ml or even larger, may be appropriate in some cases, such as where all an individual's teeth are to be whitened at once. Packaging of amounts  
5 appropriate for a single use are known in the art, for example, including pillow packs and the like.

Disposition of a whitening composition in relation to a support structure

A whitening composition may be applied to, or incorporated in, a support structure so that when the apparatus is placed in the user's mouth, the whitening  
10 composition contacts a dental surface to be whitened.

In one embodiment, the whitening composition is incorporated in the support structure from which it is extruded or leeches onto the dental surface while the patient wears the apparatus. For example, carbamide peroxide may be included in a support structure composed of an anhydrous gel such that when the support is placed in the  
15 mouth of a user, the carbamide peroxide leeches from the gel into the aqueous environment of the dental surface. In another example, a tape or strip support structure may be coated with a layer of whitening composition. Whitening composition may be applied to the support structure at anytime, such as during manufacture, or just prior to use. In another example, a tape or strip may contain microencapsulated gel-like beads  
20 containing hydrogen peroxide. This strip may be cut or separated at the desired length and applied to the tooth surface.

In a preferred embodiment, a whitening composition in the form of hydrogen peroxide microencapsulated in gel-like beads, such as alginate beads, is applied to a moldable support structure having a honeycomb-textured surface. The moldable support  
25 structure is composed of a pliant material such as wax or other material which readily conforms to the shape of the teeth. The support material may be molded by hand at room temperature or rendered moldable by application of heat. This combination has excellent delivery properties due in part to the close adaptation of the honeycomb shapes on the support surface to the smoother surface of the teeth which may be aided by Van der  
30 Walls forces between these surfaces. In use, the encapsulated whitening agent is released by application of pressure, heat or light.

### Light Sources

Light sources and wavelengths of light providing energy that promotes activation of dental whitening compositions are known in the art. For example, see U.S. Patent Nos. 4,661,070; 4,952,143; 5,032,178; 5,658,148; 5,713,738; 5,785,527; 6,056,548; 5 6,106,293; 6,149,895; 6,155,832; 6,162,055; 6,231,343; 6,287,120; 6,361,320; 6,416,319. In the context of the present invention, any light source may be used which can be incorporated into the apparatus such that the apparatus operates to whiten teeth in the closed mouth of a user without any protruding parts.

A light source may be a luminescent source, such as fluorescent, phosphorescent 10 or chemiluminescent. Other exemplary light sources include light emitting diodes and laser diodes. These light sources are powered in a manner such that the light is emitted in the mouth without external connections to a power source. For example, light emitting diodes and laser diodes operable in the present invention may be powered by an energy storage device, such as a battery or capacitor, incorporated into the apparatus. A 15 chemiluminescent source is powered by mixing appropriate chemical reactants so that a light producing reaction occurs during treatment. A fluorescent or phosphorescent source included in the apparatus is powered by exposure to exciting light so that fluorescent or phosphorescent light is emitted during dental treatment. For example, a phosphorescent source may be held under exciting light for a period of time before placement in the 20 patient's mouth for dental treatment. Alternatively, a phosphorescent source may be placed in the patient's mouth and subsequently exposed to exciting light while the patient's mouth is open. The phosphorescent afterglow then continues to activate the whitening compound after the patient closes the mouth.

Combinations of light sources are specifically contemplated as within the scope of 25 the invention. For example, a fluorescent source may be used in conjunction with a second light source, such as a phosphorescent light such that the fluorescent source is excited by the emitted phosphorescent light. Similarly, combinations of diode sources and phosphorescent or fluorescent sources may be used.

### Chemiluminescent light sources

30 A chemiluminescent light source refers to light produced by a chemical reaction. Different colors of chemiluminescent light, illustratively including blue, green and yellow, are produced according to the different chemical reactants. Examples of chemiluminescent light reactants and systems are found in U.S. Patent Nos.: 3,391,068;

- 10 -

3,511,612; 3,539,794; 3,557,233; 3,576,987; 3,584,211; 3,597,362; 3,654,525; 3,749,620; 3,752,406; 3,775,336; 3,800,132; 3,808,414; 3,888,786; 3,940,604; 3,974,368; 4,064,428; 4,313,843; 4,751,616; and 4,717,511.

Components of one type of chemiluminescent reaction include an oxalate component, an activator component and a fluorophore. Illustrative examples of an oxalate component include a phenyl oxalate ester such as dibutyl phthalate, bis (2,4,5-trichloro-6-carbopentexyphenyl) oxalate, bis (2,4-dinitrophenyl) oxalate (DNPO) and bis (2,4,6-trichlorophenyl) oxalate. Illustrative examples of an activator include dimethyl phthalate, t-butyl alcohol, hydrogen peroxide and sodium salicylate. Examples of fluorophores used in chemiluminescent reactions include 1-chloro-9, 10-bis (phenylethynyl) anthracene, 9,10-diphenylanthracene, Rhodamine B, 5,12-Bis (phenylethynyl)-naphthacene and tetraphenylanthracene. Further chemiluminescent systems may be based on dioxetanes, luminols, acridinium esters and aryloxalates, as described in H. Akhavan-Tafti, et al., *Chemiluminescent Haloalkoxy-substituted Dioxetanes: Properties and Applications*, in *Bioluminescence and Chemiluminescence Molecular Reporting with Photons*, J. W. Hastings, L. Kricka and P. Stanley, Eds., John Wiley and Sons, Chichester, 497-500 (1997) and *Bioluminescence and Chemiluminescence: Progress and Current Applications* Robinson by Phillip E. Stanley (Editor), Larry J. Kricka (Editor), World Scientific Pub Co; 2002. Other chemiluminescent light sources include bioluminescent systems such as those taught in U.S. Patent No. 5,876,995.

Components of chemiluminescence reactions are provided in separate containers and the components combined when chemiluminescent light production is desired. Glow sticks and glow tubes are examples of available commercial packaging for chemiluminescent materials. Typically, such packaging includes a breakable multi-compartment internal container, each enclosing a chemical reactant or stable mixture of selected reactants. The internal containers are surrounded by an outer container such that by breaking the internal containers, the reactants are mixed and held within the outer container. For example, a phenyl oxalate ester and a fluorophore may be stored together in one compartment, and hydrogen peroxide in another compartment, the compartments broken in order to mix the reactants and produce light.

In another embodiment, an oxalate compound and a fluorophore may be stored together in one inner compartment, and a hydrogen peroxide containing composition is present within the outer container, such that the inner compartments broken in order to

- 11 -

mix the reactants within the outer container and produce light. The contents of this container may then be applied to a support or dental surface as a light source. Additionally, it will be appreciated that the hydrogen peroxide present in a light source of this type is also a whitening composition.

5 In one embodiment, a chemiluminescent light source is provided in microencapsulated form. Reaction components are separately incorporated into microcapsules, such as alginate beads. Components are mixed by placing reaction component containing beads in proximity and releasing the components from the beads by application of pressure, dissolution of the capsule barrier, warming or similar release  
10 methods known in the art, such that the components react and produce light. For example, in accordance with the invention, an oxalate compound and a fluorophore may be stored microencapsulated together, and hydrogen peroxide microencapsulated separately. These two forms of microcapsules are applied to a support, such as a honeycomb textured moldable sheet, or directly to a dental surface. A chemiluminescent  
15 reaction may then be initiated by releasing the reaction components from the microcapsules. The reaction components are thus mixed, initiating the chemiluminescent reaction and producing light. One of skill in the art will recognize that other combinations of chemiluminescent reactants are operable in this embodiment. It is appreciated that a hydrogen peroxide solution used in this context as a component of a  
20 chemiluminescent reaction, is also a whitening composition component.

In another embodiment, one component of a chemiluminescence reaction may be microencapsulated and other reactants provided in another form. The microspheres are permeabilized so that the reactants contained therein are released into contact with the other reactants, allowing the chemiluminescent reaction to occur. For example,  
25 microspheres containing an oxalate compound and a fluorophore may be applied to a support, such as a honeycomb textured moldable sheet, or directly to a dental surface. A hydrogen peroxide containing liquid, gel, emulsion, putty, paste or the like is also applied to the support or dental surface. The microencapsulated components are released, by application of pressure, enzymatic or solvent mediated dissolution of the capsule barrier,  
30 warming or similar release methods known in the art. Released microencapsulated components then react with the other reaction components so that a chemiluminescent reaction occurs. One of skill in the art will recognize that other combinations of chemiluminescent reactants are operable in this embodiment. It is appreciated that a

hydrogen peroxide solution used in this context as a component of a chemiluminescent reaction, is also a whitening composition component.

In a further embodiment, as described above, one component of a chemiluminescence reaction may be microencapsulated and other reactants provided in another form, such as a solution. In this case, the microspheres are made permeable to a molecule of selected size, in order to allow other reactants to diffuse into the microspheres but preventing release of microencapsulated components. The interaction of the reaction components initiates a light producing reaction inside the microspheres. For example, microspheres containing an oxalate compound and a fluorophore may be applied to a support, such as a honeycomb textured moldable sheet, or directly to a dental surface followed with a hydrogen peroxide containing liquid, gel, emulsion, putty or paste. In this case, the microspheres are made permeable to molecules of selected size, in order to allow hydrogen peroxide to diffuse into the microspheres but not allowing release of the oxalate compound and fluorophore. One of skill in the art will recognize that other combinations of chemiluminescent reactants are operable in this embodiment. It is appreciated that a hydrogen peroxide solution used in this context as a component of a chemiluminescent reaction, is also a whitening composition component.

It will be evident to one of skill in the art that separately packaged chemiluminescence reaction components may be mixed to initiate the light producing reaction before application to a support or dental surface if desired. For example, chemiluminescent reaction components may be packaged in separate compartments within a dispensing device such as a plastic bottle or tube. The barrier between the separate compartments may be broken by pressure, heat or the like, and the reactants mixed to initiate the chemiluminescence reaction within the dispensing device. The light producing reaction mixture, in the form of a liquid, gel or the like, may then be dispensed onto the support or the dental surface as desired.

#### Phosphorescent light sources

Phosphorescent materials are those, which are excited by UV or visible light, resulting in the emission of light that lasts after the exposure to the exciting light has ceased. Duration of the emission is typically from minutes to hours, but can even extend for several days. Many useful phosphorescent materials occur naturally or have been developed, including both inorganic and organic compounds.

- 13 -

Common inorganic phosphorescent materials suitable for use as a light source in the present invention include a metal cation, a non-metal anion and an "activator". Examples of suitable inorganic phosphors include sulfides, metal aluminate oxides, silicates and various rare earth compounds. For instance, as is known in the art, ZnS and

5 ZnS may be combined with various activators such as aluminum, cerium, copper, europium, gadolinium, gallium, gold, indium, lead, manganese, praseodymium, samarium, scandium, silver, terbium, and other rare earth elements and halogens to produce a phosphorescent material, and these may be used as a light sources in the invention. Further examples of sulfide phosphors illustratively include alpha barium-zinc

10 sulfides, barium-zinc-cadmium sulfides,  $\text{CaS:Bi}$ ,  $\text{CaSrS:Bi}$ , strontium sulfides,  $\text{ZnCdS:Cu}$  and  $\text{ZnCdS:Ag}$ . Metal aluminate oxides include alkaline earth aluminate oxides, such as strontium aluminum oxide, calcium aluminum oxide and barium aluminum oxide. Strontium aluminate with a europium activator ( $\text{SrAlO}_3\text{:Eu}$ ) is an exemplary phosphorescent material suitable for use as a light source in an inventive

15 apparatus. Further oxide phosphorescent materials that illustrate phosphorescent materials that may be used as a light source in the invention include aluminum oxides, boric oxides, calcium oxides, dysprosium oxides, europium oxides and strontium oxides. Further examples of phosphorescent materials include those taught in U.S. Patent Nos. 3,595,804; 3,957,678; 3,970,582, 5,376,303, 5,424,006, 5,558,817 and 5,853,614.

20 Examples of phosphorescent organic materials are found in U.S. Patent Nos. 5,229,16 and 5,618,467. Any of these listed phosphorescent materials, mixtures thereof, and art recognized equivalents may be used as a light source in an apparatus according to the present invention.

Preferred phosphorescent light sources are those having long-lasting light

25 emission. For example, strontium aluminate with a europium activator ( $\text{SrAlO}_3\text{:Eu}$ ) is a suitable long-lasting emitter, having an emission time of about 10 hours following exposure to exciting light.

Phosphorescent materials suitable for use in an inventive apparatus are commercially available, illustratively including those manufactured and sold under the

30 brand name Picariko by Chemitech, Inc., Tokyo and available from F. W. Bass International; those made by Nemoto & Company, Tokyo and available from United Mineral & Chemical Corporation, Lyndhurst, N.J. under the brand name LumiNova. Further, PermaglowR products by Chemitech Inc., Tokyo such as Natural Blue color,

- 14 -

having a peak emission at 489, produced as particles having 30-65 micron size is a suitable phosphorescent material used as a light source in an inventive apparatus. Sizes outside this range may also be workable.

#### Fluorescent light sources

5 Fluorescent light sources suitable for use in an inventive apparatus illustratively include such compounds as the commercially available coumarin dyes such as Fluorescent Yellow FP, Macrolex Fluorescent Yellow 10GN, and Fluorescent Red G; (Bayer); Thermoplast Yellow 084 (BASF), and Solvent Orange 63, HOSTASOL Solvent  
10 Yellow 98, and Vat Red 41, (Clariant Corp.) and LUMOGEN F Dyes manufactured by BASF Corporation as well as art recognized equivalents.

#### Diode light sources

Diode light sources suitable for use in an inventive apparatus include both light emitting diodes and laser diodes. Diodes and methods of their incorporation into a support structure for use in an internal body cavity are known in the art and includes  
15 those described in U.S. Patent Nos. 5,500,009; 5,702,432; 5,989,245; 6,077,073 and 6,439,888. Of particular interest are individual diodes and diode arrays that are incorporated into a support structure along with a power source, see for example, U.S. Patent No. 5,445,608.

#### Disposition of a light source in relation to a support structure

20 A light source may be disposed on and/or in the support structure so that light emitted from the light source impinges on the whitening composition.

In another embodiment, a light source is made integral to the support by being included in a material forming the support structure. In an embodiment shown in Figure 3A, a luminescent material light source 20 is integral to the support structure 22. Also  
25 shown is a dental whitening composition 24 which is contacted by light 26 emitted by the light source 20. The dental whitening composition is shown in contact with a dental surface 28. Methods and compositions for forming luminescent articles by including a luminescent material in a resin, plastic, wax, sheet material or other support structure forming material are known in the art, for example, as described in 3,796,668; 4,211,813;  
30 4,629,583; 4,707,297; 4,911,830; 5,464,651; 5,618,467; 5,783,108; 5,914,076 and 6,375,864.

Alternatively, a diode or luminescent material may be disposed on an external surface of a support. In an embodiment shown in Figure 3B, a light source 20 is present

- 15 -

on an external surface of a support structure 22. Also shown is a dental whitening composition 24 which is contacted by light 26 emitted by the light source 20. The dental whitening composition is shown in contact with a dental surface 28. Figure 3C illustrates an arrangement wherein the light source 20 is on a surface of the support structure 22  
5 distal to the dental surface 28 which is in contact with the whitening composition 24. A light source disposed on a support structure may have various forms illustratively including a diode and a luminescent material in the form of a gel, gum, emulsion, putty, liquid paint, varnish, curable resin, wax, tape, glow tube, glow stick or paste which can be applied to a support. Methods and compositions for such luminescent compositions  
10 are known in the art and are disclosed herein.

A diode and its power source may be applied to a support structure surface by conventional methods illustratively including adhesive fixation. Similarly, a luminescent light source in may be affixed to a support using an adhesive. Suitable adhesives and their use are known in the art and preferably include food grade adhesives such as  
15 Spectrum 0172, available from the Velcro Group Corporation, and those materials disclosed in U.S. Patent Nos. 3,527,646; 4,504,502; 4,910,031; 4,913,919; 4,981,707; 5,275,830; 5,275,831 and 5,298,268.

Optionally, a protective material covers the light source and/or whitening composition. For example, a layer of a sheet material, such as polypropylene,  
20 polyvinylidene chloride, polyethylene and the like, is placed over the light source and/or whitening composition. The protective material may be placed over a whitening composition for instance where the composition is applied to the support in advance of use, such as during manufacture, so as to protect the composition from dehydration, exposure to light, air and the like. The protective material may then be removed just prior  
25 to use.

Similarly, an optional protective material may be disposed so as to cover a light source in order to aid in securing in the light source to the support and to protect the light source from the environment. In one embodiment, a light source includes a phosphorescent powder affixed to a surface of a moldable sheet material support  
30 structure using an adhesive. Optionally, a protective sheet material is affixed to the same surface of the support structure after application of the phosphorescent powder. The protective sheet material aids in keeping the phosphorescent powder in place on the support and protects the powder from exposure to the environment. The protective sheet



- 16 -

material may be translucent to allow excitation of the light source and /or emission of the phosphorescent light.

A light source may be disposed on, integral to, or in a support structure in multiple forms in an inventive apparatus. For instance, a light source may be  
5 incorporated in a material included in or forming the support structure. In addition, a light source may be applied to the support structure.

Advantageously, a light source may be disposed in relation to the support such that only teeth to be treated are exposed to the light. For example, a light source in the form of a gel may be placed in proximity to a subset of teeth. Similarly, a diode source  
10 may be positioned where desired on a support such that light is directed primarily a certain tooth or dental surface to be treated.

Further, a light source may be placed so that multiple surfaces of a tooth may be treated simultaneously. For example, a support incorporating a luminescent substance may be formed to fit the individual's dentition so that both the front and back surfaces of  
15 a tooth are exposed to a whitening compound and activating light. No known light-activated system allows for simultaneous light accelerated whitening of the front and back of a tooth with no protruding parts (i.e., with the mouth closed).

A luminescent material or diode may be partially or wholly surrounded by support structure material such that light is transmitted through the support structure to  
20 the dental whitening composition. In one embodiment of this arrangement (not shown), a chemiluminescent light source may be located in an interior chamber of the support structure such as a fluid-tight internal cavity for a chemical reactant. The internal cavity is sub-divided into at least two compartments, each containing a chemical reactant. The compartments are separated by an internal divider which can be broken so as to mix the  
25 chemical reactants such that a chemiluminescent reaction occurs, producing light.

In an embodiment shown in Figure 3D, a light source 20 is integral to support structure 22. The light source 20 emits light 26 which travels toward the dental whitening composition 24 as well as light 30 traveling in other directions. A reflective material 32 included in the apparatus 40 directs light 31 toward the whitening  
30 composition.

#### Size of dental apparatus

The dental apparatus is sized to fit entirely within the mouth of a patient while the patient undergoing dental whitening. Thus, the support structure, whitening composition

- 17 -

and light source are in place and operable while the patient's mouth is closed. Further, because it is not necessary to attach the apparatus to an external power source during treatment, the patient can move freely and go about normal activities without any wires, fibers, batteries or other connections, such as to a power or light source, protruding or  
5 extending outside the mouth in the course of treatment. Typical size of an apparatus is ranges from about 0.5 cm<sup>3</sup> to about 450 cm<sup>3</sup> and is less than the volume of an average adult human oral cavity which ranges from about 100 to 500 cm<sup>3</sup>.

#### Method of Treating a Dental Surface

As illustrated in Figure 4A, a method of treating a dental surface includes the step  
10 50 of providing a dental apparatus wherein the apparatus includes a support structure, a dental whitening composition, and a light source. In another step 52 the light source included in the apparatus is activated such that light is emitted. Activation of the light source to emit light depends on the type of light source. For example, a diode may be activated by an on/off switch which in the "on" position makes an electrical connection  
15 between the diode and a power source. A phosphorescent or fluorescent source may be activated by exposure to exciting light of an appropriate wavelength for the phosphorescent material used. A chemiluminescent source is activated by mixing appropriate chemical reactants. In a further step 54 apparatus is placed entirely within the mouth of a patient using the apparatus such that the individual can close the mouth  
20 comfortably and no part of the apparatus remains outside the mouth. In a subsequent step 56, the dental surface is exposed to light emitted from dental apparatus, thereby treating the dental surface. As shown in Figure 4B, step 52 wherein the light source is activated may be performed before or after step 54 wherein the apparatus is placed in the patient's mouth depending on comfort, convenience and safety considerations.

25 The dental surface is exposed to light emitted from dental apparatus for a period of time effective to whiten the dental surface. Typical exposure times range from 1 minute to 24 hours depending on the whitening composition used and the light source.

A user of an inventive apparatus or method is any mammal, typically a human.

While the inventive apparatus and method is described herein as including a  
30 support structure, it is appreciated that a whitening composition and illumination source may be applied to a dental surface to be treated without a support structure. For example, a luminescent compound and a whitening composition may be included together in a

- 18 -

suitable form, such as a gel, liquid, putty, tape or gum which is applied directly to a dental surface to be treated.

### Example

In one embodiment of an inventive apparatus, shown in Figure 5, a support structure having a generally described U-shape is shown at 200. A textured surface 202 is shown including hexagonal cells 204. The cells 204 act as reservoirs for delivery of whitening compositions and here are shown containing beads 206 which enclose a whitening composition, such as hydrogen peroxide in a concentration ranging from 3 – 35%. A phosphorescent light source (not shown) is integral to the support shown, such that when an exciting light is directed at the support for a period of time, the support glows for a period after the exciting light is removed.

Although the invention is described as appropriate for delivering a dental whitening composition and for use in a method for whitening teeth, it is appreciated that a support structure as described herein may be used to deliver other treatments via an oral route. For example, therapeutic agents to treat dental or systemic diseases or conditions, such as anti- plaque agents, anesthetics, desensitizing agents, analgesics, antibiotics, antifungals, antimicrobials, antivirals, anti-inflammatory agents, remineralizing agents, anticarcinogenic agents and steroids may be delivered using a support structure with or without an illumination source.

Any patents or publications mentioned in this specification are indicative of the levels of those skilled in the art to which the invention pertains. These patents and publications are herein incorporated by reference to the same extent as if each individual publication was specifically and individually indicated to be incorporated by reference.

One skilled in the art will readily appreciate that the present invention is well adapted to carry out the objects and obtain the ends and advantages mentioned, as well as those inherent therein. The present methods, procedures, treatments, molecules, and specific compounds described herein are presently representative of preferred embodiments, are exemplary, and are not intended as limitations on the scope of the invention. Changes therein and other uses will occur to those skilled in the art which are encompassed within the spirit of the invention as defined by the scope of the claims.

I claim:

1. A dental apparatus, the apparatus comprising:
  - 2 a support structure adapted to be placed entirely within a user's mouth;
  - a dental whitening composition in contact with the support structure; and
  - 4 a light source disposed on or in the support structure such that light emitted from the source impinges on the dental whitening composition, wherein the apparatus has a
  - 6 volume between 0.5 – 450 cm<sup>3</sup>.
2. The dental apparatus of claim 1, wherein the dental whitening composition
- 2 comprises an oxidizing agent.
3. The dental apparatus of claim 2, wherein the oxidizing agent is a peroxide.
4. The dental apparatus of claim 1, wherein the whitening composition is in a
- 2 form selected from the group consisting of: gel, emulsion, gum, putty, liquid and paste.
5. The dental apparatus of claim 1, wherein the whitening composition is in a
- 2 microencapsulated form.
6. The dental apparatus of claim 5, wherein the microencapsulated form is
- 2 selected from the group consisting of: agar gel beads, liposomes and niosomes.
7. The dental apparatus of claim 1, wherein the light source comprises a
- 2 luminescent material selected from the group consisting of: phosphorescent, fluorescent, chemiluminescent and combinations thereof.
8. The dental apparatus of claim 7, wherein the light source further
- 2 comprises a diode.
9. The dental apparatus of claim 1, wherein the light source comprises a
- 2 diode selected from the group consisting of: light emitting diode and laser diode.
10. The dental apparatus of claim 1, wherein the support structure is a dental
- 2 strip.

- 20 -

11. The dental apparatus of claim 1, wherein the support structure is a dental  
2 tray.

12. The dental apparatus of claim 1, wherein the light source is a luminescent  
2 material having a form selected from the group consisting of: gel, gum, emulsion, putty,  
liquid, powder, crystalline solid, varnish, curable resin and paste.

13. The dental apparatus of claim 1, wherein the light source is integral to the  
2 support.

14. The dental apparatus of claim 1, further comprising a reflective material  
2 disposed on or in the support structure such that light is reflected toward the whitening  
composition.

15. The dental apparatus of claim 1, wherein the support structure comprises a  
2 textured surface.

16. The dental apparatus of claim 15, wherein the textured surface comprises  
2 a hexagonal cell.

17. The dental apparatus of claim 1, wherein the light source comprises a  
2 microencapsulated chemiluminescence reaction component.

18. The dental apparatus of claim 17, wherein the microencapsulated  
2 chemiluminescence reaction component is selected from the group consisting of: an  
oxalate compound, a fluorophor, a peroxide and a combination thereof.

19. A method for treating a dental surface of a user comprising the steps of:  
2 (a) providing a dental apparatus comprising: a support structure adapted to be  
placed entirely within the user's mouth;  
4 a dental whitening composition in contact with the support structure; and a light  
source disposed on or in the support structure such that light emitted from the source

- 21 -

- 6 impinges on the dental whitening composition, wherein the apparatus has a volume  
between 0.5 – 450 cm<sup>3</sup>;
- 8 (b) activating the light source such that light is emitted by the light source;
- (c) placing the apparatus entirely within the user's mouth; and
- 10 (d) exposing the dental surface to the light emitted by the light source, thereby  
treating the dental surface.

20. The dental apparatus of claim 19, wherein the dental whitening  
2 composition comprises an oxidizing agent.

21. The dental apparatus of claim 20, wherein the oxidizing agent is a  
2 peroxide.

22. The dental apparatus of claim 19, wherein the whitening composition is in  
2 a form selected from the group consisting of: gel, emulsion, gum, putty, liquid and paste.

23. The dental apparatus of claim 19, wherein the light source comprises a  
2 luminescent material selected from the group consisting of: phosphorescent, fluorescent,  
chemiluminescent and combinations thereof.

24. The dental apparatus of claim 23, wherein the light source further  
2 comprises a diode.

25. The dental apparatus of claim 19, wherein the light source comprises a  
2 diode selected from the group consisting of: light emitting diode and laser diode.

26. The dental apparatus of claim 19, wherein the support structure is a dental  
2 strip.

27. The dental apparatus of claim 19, wherein the support structure is a dental  
2 tray.

- 22 -

28. The dental apparatus of claim 19, wherein the light source is a luminescent  
2 material having a form selected from the group consisting of: gel, gum, emulsion, putty,  
liquid, varnish, curable resin and paste.

29. The dental apparatus of claim 19, wherein the light source is integral to  
2 the support.

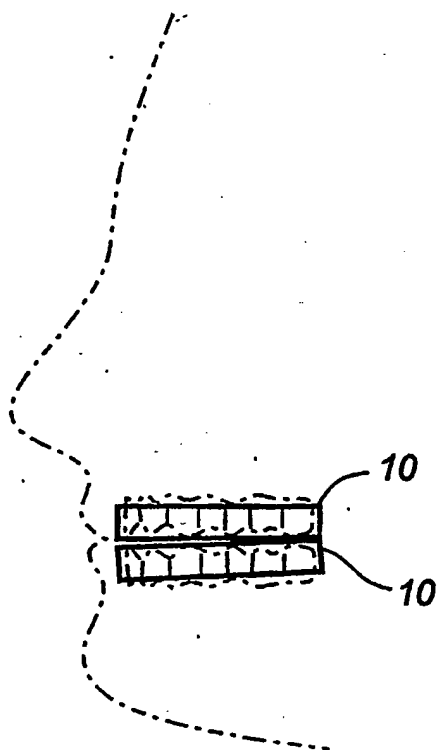
30. The dental apparatus of claim 19, further comprising a reflective material  
2 disposed on or in the support structure such that light is reflected toward the whitening  
composition.

31. The dental apparatus of claim 19, wherein the support structure comprises  
2 a textured surface.

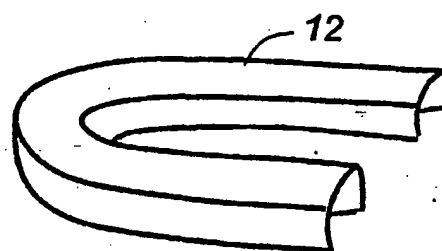
32. The dental apparatus of claim 31, wherein the textured surface comprises  
2 a hexagonal cell.

33. The dental apparatus of claim 19, wherein the light source comprises a  
2 microencapsulated chemiluminescence reaction component.

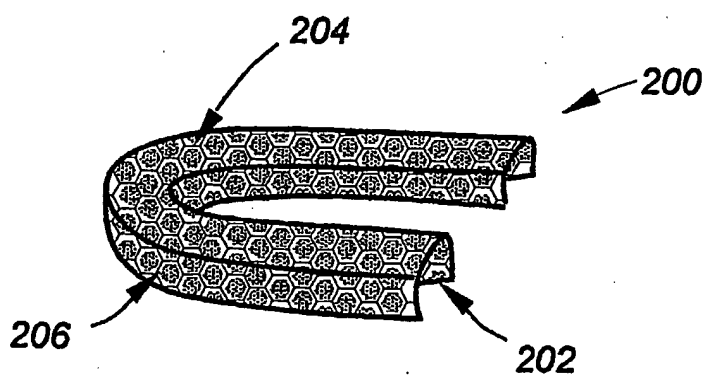
34. The dental apparatus of claim 19, wherein the microencapsulated  
2 chemiluminescence reaction component is selected from the group consisting of: an  
oxalate compound, a fluorophor, a peroxide and a combination thereof.



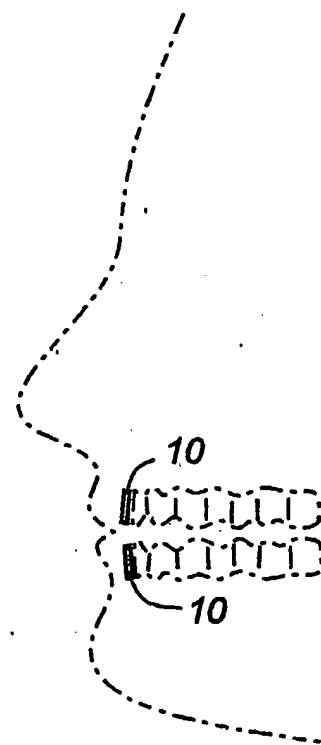
**Fig - 1A**



**Fig - 1B**

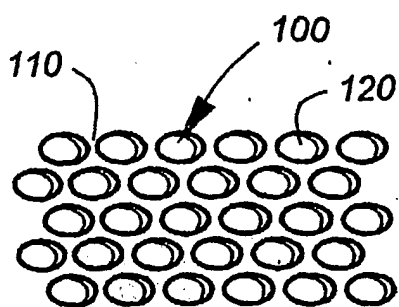


**Fig - 5**

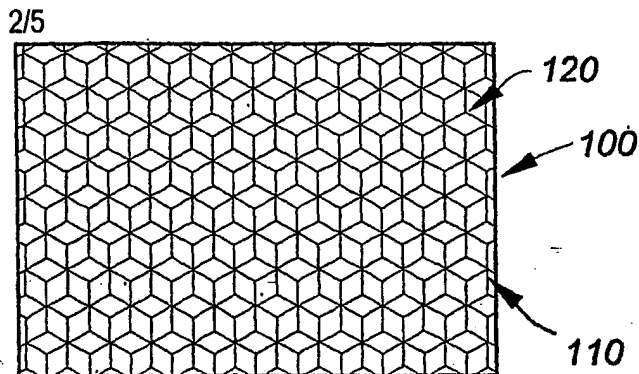


**Fig - 2A**

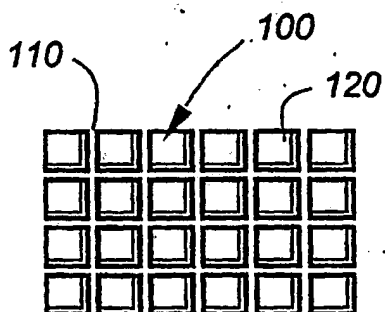




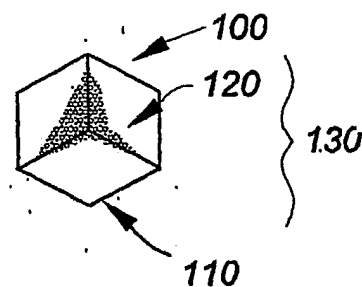
**Fig - 2B**



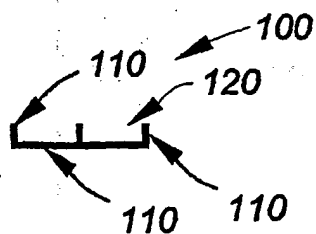
**Fig - 2D**



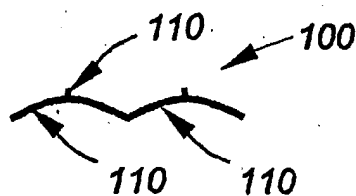
**Fig - 2C**



**Fig - 2E**

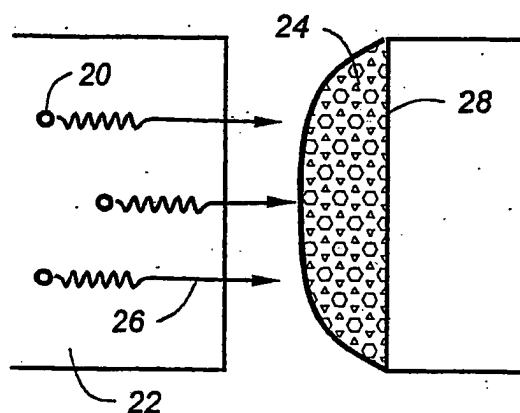
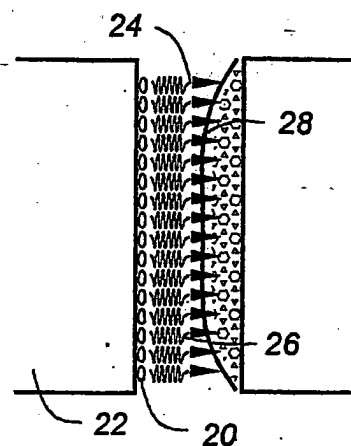
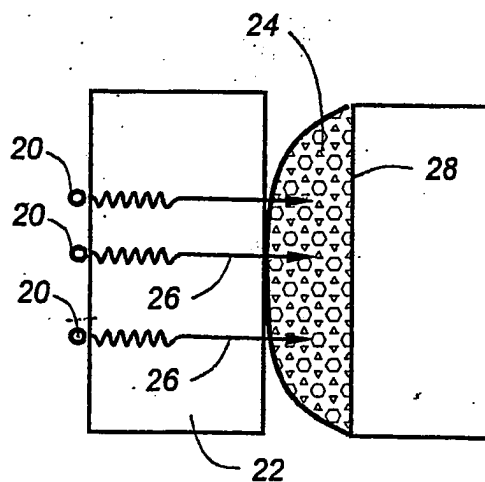
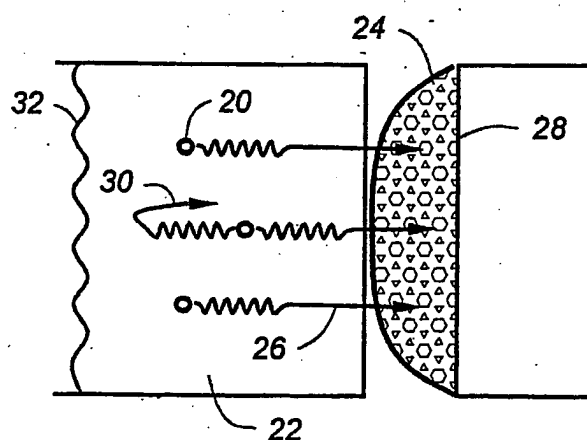


**Fig - 2G**



**Fig - 2F**

3/5

**Fig - 3A****Fig - 3B****Fig - 3C****Fig - 3D**

4/5

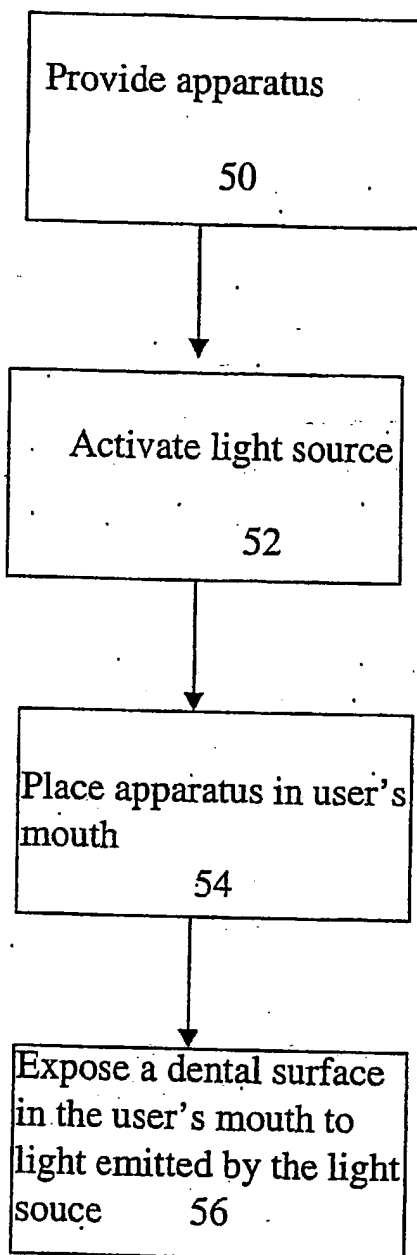


FIGURE 4A

5/5

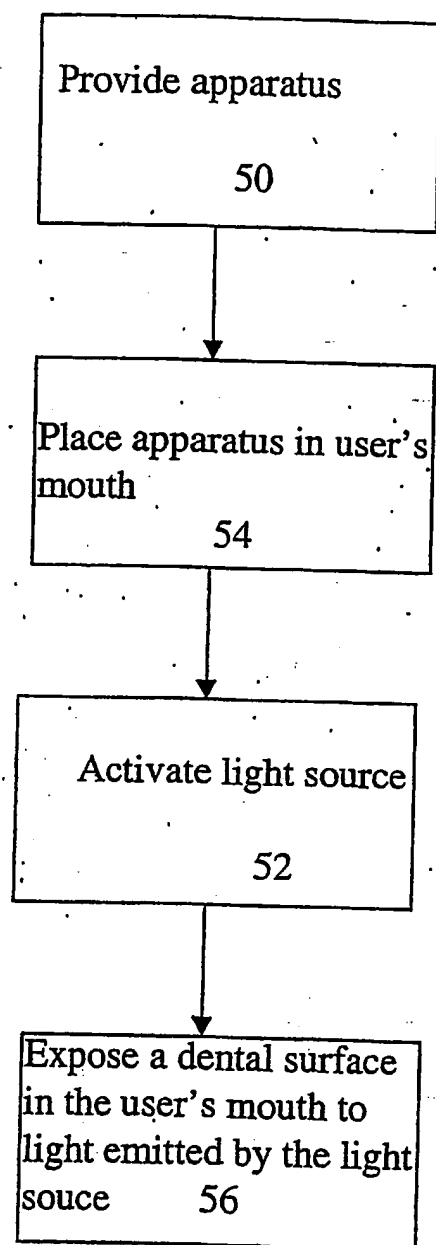


FIGURE 4B

SUBSTITUTE SHEET (RULE 26)

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property  
Organization  
International Bureau



(43) International Publication Date  
17 June 2004 (17.06.2004)

PCT

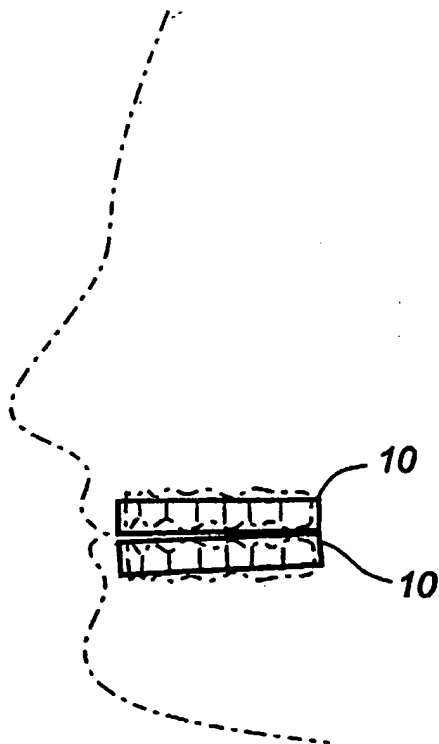
(10) International Publication Number  
**WO 2004/049966 A3**

- (51) International Patent Classification<sup>7</sup>: **A61C 003/00**
- (21) International Application Number:  
PCT/US2003/038427
- (22) International Filing Date: 3 December 2003 (03.12.2003)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:  
10/309,831 4 December 2002 (04.12.2002) US
- (71) Applicant and  
(72) Inventor: **WASYLUCHA, Bryan** [US/US]; 2222 Michelson Drive, #222-447, Irvine, CA 92612 (US).
- (74) Agents: **POSA, John, G. et al.**; Gifford, Krass, Groh, Sprinkle, Anderson & Citkowski, P.C., 280 N. Old Woodward Avenue, Ste. 400, Birmingham, MI 48009 (US).
- (81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (*regional*): ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).
- Published:  
— with international search report

[Continued on next page]

(54) Title: **METHOD AND APPARATUS FOR BLEACHING TEETH**

(57) Abstract: A method and apparatus for whitening teeth which allow the user to undergo dental bleaching with the mouth closed and without protruding instruments, trays or electrical wires and the like. The apparatus includes a support structure and a dental whitening composition in contact with the support structure. A light source is included in the apparatus, disposed on or in the support structure so that light emitted from the source contacts on the dental whitening composition. The apparatus has a volume ranging between 0.5 - 450 cm<sup>3</sup> permitting the apparatus to fit entirely within the mouth of a user during treatment.



WO 2004/049966 A3



(88) Date of publication of the international search report:  
30 September 2004

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/38427

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61C 003/00

US CL : 433/29, 37, 38, 80, 39, 34, 42, 216

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 433/29, 37, 38, 80, 39, 34, 42, 216

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched  
NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
NONE

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X, P — Y, P	US 6,616,447 B1 (RIZOIU et al.) 09 September 2003 (09.09.2003), See the entire document.	1-4, 7-14 and 19-30 5-6, 15-18 and 31-34.
Y	US 6,435,873 B1 (BURGIO) 20 August 2002 (20.08.2002), See the entire document.	15, 16, 31 and 32
Y	US 5,403,578 A (GORDON) 04 April 1995 (04.04.1995), See the entire document.	5 and 6
Y	US 5,718,577 A (OXMAN et al.) 17 February 1998 (17.02.1998), See the entire document.	17, 18, 33 and 34
A	US 5,316,473 A (HARE) 31 May 1994 (31.05.1994), See the entire document.	1-34

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:	
"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E" earlier application or patent published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

17 May 2004 (17.05.2004)

Date of mailing of the international search report

09 JUL 2004

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Facsimile No. (703) 305-3230

Authorized officer

Linda Sholl

Telephone No. 703 308 1148

Form PCT/ISA/210 (second sheet) (July 1998)